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In re Application of :
John B. Classen :
Serial No.: 08/591,651 : PETITION DECISION
Filed: February 12, 1996 :
Attorney Docket No.: CLASSEN=1A :

This is a decision on the petition under 37 CFR 1.181 and conditional petition under 37 CFR 1.183, both filed December 12, 2002, to require the examiner to enter and give full consideration to a declaration filed under 37 CFR 1.132.

BACKGROUND

A review of the extensive file history shows that this application is the National Phase filing of PCT/US94/08825, filed August 4, 1994, which is the effective filing date of the application. The application was accorded status under 35 U.S.C. 371 on February 12, 1996. Two preliminary amendments and those made during the International Phase of the application resulted in the cancellation of claims 1, 3-4, 7, 12-13, 18, 20, 23-24, and the addition of claims 31-55. The first examiner mailed applicant a first Office action on October 2, 1998, setting a three month shortened statutory period for reply. The Office action rejected claims 2-17 (sic 2, 5-6, 8-11, 14-17), 19, 21, 23-33 (sic 25-33), and 34-55 under 35 U.S.C. 112, first paragraph for lack of enablement; claims 2-19 (sic 2, 5-6, 8-11, 14-17 and 19), and 21 under 35 U.S.C. 112, second paragraph for indefiniteness; claims 2-4 (sic 2), 6-17 (sic 6, 8-11, 14-17), 19, 21, 23-33 (sic 25-33), 34-43 and 45-55 under 35 U.S.C. 102(b) as anticipated by Madore et al; claims 2-4 (sic 2), 6-17 (sic 6, 8-11, 14-17), 19, 21, 23-33 (sic 25-33), 34-55 under 35 U.S.C. 102(b) as anticipated by Dengrove et al; claims 2-4 (sic 2), 6-17 (sic 6, 8-11, 14-17), 19, 21, 23-33 (sic 25-33), 34-55 under 35 U.S.C. 102(b) as anticipated by Halsey et al; claims 2-4 (sic 2), 6-17 (sic 6, 8-11, 14-17), 19, 21, 23-33 (sic 25-33), 34-55 under 35 U.S.C. 102(b) as anticipated by Jacob John; claims 25-27, 34-36, 38-47 and 49 under 35 U.S.C. 102(b) as anticipated by Chazono et al; and claims 2-4 (sic 2), 6-17 (sic 6, 8-11, 14-17), 19, 21, 23-33 (sic 25-33), 34-55 for obvious double patenting.

Applicant replied on March 25, 1999, by canceling claims 2, 9, 14, 17, 21, 25, 31, 42, 45, 47, 53 and 54, amending a number of other claims and adding claims 56-101. Appropriate arguments for each rejection were set forth and an affidavit by the inventor under 37 CFR 1.132 was presented to provide evidence with respect to the enablement rejection.

Due to changes in personnel, the application was assigned to a new examiner who mailed applicant a Final Office action on May 4, 1999. The examiner maintained the obvious double patenting rejection of claims 2-17 (sic 5-6, 8, 10-11 and 15-16), 19, 21 (sic), 23-33 (sic 26-30, 32-33), and 34-55 (sic 34-41, 43-44, 46, 48-52 and 55) and added claims 56-58 and 101 to the rejection. The rejection under 35 U.S.C. 112, first paragraph, for claims 5-6, 8, 10-11, 15-16, 19, 26-30, 32-41, 43-44, 46, 48-52, and 55 and newly added claims 56-101 was maintained for reasons of record. The rejection under 35 U.S.C. 112, second paragraph, for claims 5-6, 8, 10-11, 15-16 and 19 was maintained and further applied to claims 65-101. Claims 6, 21 (sic), 32 and 33 were again rejected under 35 U.S.C. 102(b) over Madore et al; claims 8, 10-11, 15-16, 19, 26-30, 34-41, 43-44, 46, 48-52, and 55 and new claims 59-100 were again rejected under 35 U.S.C. 102(b) over Madore et al; claims 5-6, 8, 10-11, 15-16, 19, 26-30, 32-41, 43-44 and 46-52 and new claims 56-101 were again rejected under 35 U.S.C. 102(b) over Dengrove et al; claims 5-6, 8, 10-11, 15-16, 19, 26-30, 32-41, 43-44 and 46-52 and new claims 56-101 were again rejected under 35 U.S.C. 102(b) over Halsey et al; claims 5-6, 8, 10-11, 15-16, 19, 26-30, 32-41, 43-44 and 46-52 and new claims 56-100 were again rejected under 35 U.S.C. 102(b) over John; claims 26-27, 34-36, 38-41, 43-44 and 46 and new claims 56-100 were again rejected under 35 U.S.C. 102(b) over Chazono et al. Claims 6, 32 and 101 were newly rejected under 35 U.S.C. 112, first paragraph for lack of description of newly added limitations in the specification. Claims 5, 8, 10, 11, 30, 38, 49, 55, 60-65 and 72-100 were again rejected under 35 U.S.C. 112, first paragraph, for lack of enablement.

Applicant filed a request to withdraw the finality of the Office action on June 14, 1999. This was followed by an amendment after final Office action, filed September 7, 1999, which was entered in the file and an additional affidavit by the inventor under 37 CFR 1.132, and a Supplemental amendment which added claims 102-108, also filed September 7, 1999, which was not entered.. No other amendments were made. The examiner replied with an Advisory Action mailed September 29, 1999, which dismissed applicant's request to withdraw the finality of the Office action and presented reasons for maintaining finality. The rejection of claims 6, 21, 32 and 33 under 35 U.S.C. 102(b) over Madore et al was withdrawn. The rejection of claims 5, 8, 10, 11, 30, 38, 49, 55, 60-65 and 72-100 under 35 U.S.C. 112, first paragraph, was also withdrawn.

Applicant replied on October 28, 1999, with a second request to withdraw the finality of the Office action and for an interview and further comments/arguments of the rejections. A Notice of Appeal was filed on November 4, 1999. An interview was held by telephone on December 1, 1999, in which the rejections were discussed. A further response to the Advisory Action and interview was filed December 21, 1999. The examiner issued another Advisory Action on March 13, 2000, maintaining the finality of the Office action with arguments therefor and of all pending rejections. Applicant filed an Appeal Brief on May 1, 2000.

In response to the Appeal Brief, the examiner withdrew the finality of the previous Office action and reopened prosecution by mailing a non-final Office action to applicant on June 20, 2000. All previously unentered amendments should have been entered. All previous rejections under 35 U.S.C. 112, first or second paragraphs, were withdrawn. New rejections were set forth as follows: Claims 5-6, 19, 30, 32, 37, 56-58, 67, 69-71, 73 and 75-77 were objected to for specific informalities. Claims 5-6, 8-11, 15-16, 19, 26-30, 34-57, 77 and 86 were newly rejected under 35 U.S.C. 112, second paragraph, for indefiniteness with specific deficiencies being pointed out. Claims 5-6, 8-11, 16, 30, 32, 38, 49, 55-65, 72 and 74-101 were rejected under 35 U.S.C. 112, first paragraph, for lack of written description/new matter in the specification, with specific problems being pointed out. Claims 5-6, 8, 10-11, 15-16, 19, 26-30, 32-41, 43-44, 46, 48-52 and 55-101 were rejected under 35 U.S.C. 112, first paragraph, as lacking enablement in the specification. Claims 2-17 (sic 5-6, 8, 10-11 and 15-16), 19, 21, 23-33 (sic 25-33), 34-55, 56-58 and 101 were rejected for obvious double patenting. Claims 8, 10-11, 15-16, 19, 26-30, 34-41, 43-44, 46, 48-52, 55, 59-67, 72-73, 76-77, 79, 89-90, 92, 9 (sic 93(?)) and 96-100 were rejected under 35 U.S.C. 102(b) as anticipated by Madore et al. Claims 5-6, 8, 10-11, 15-16, 19, 26-30, 32-41, 43-44, 46-52, 59-67, 70-73, 76, 78-79, 90, 92-93 and 96-100 were rejected under 35 U.S.C. 102(b) as anticipated by Dengrove et al. Claims 5-6, 8, 10-11, 15-16, 19, 26-30, 32-41, 43-44, 46-52, 59-67, 70-73, 76, 78-79, 90, 92-93 and 96-100 were rejected under 35 U.S.C. 102(b) as anticipated by Halsey et al. Claims 5-6, 8, 10-11, 15-16, 19, 26-30, 32-41, 43-44, 46-52, 60-67, 70, 72-73, 78-79, 90-91 and 96-100 were rejected under 35 U.S.C. 102(b) as anticipated by John. Claims 5, 8, 10-11, 15-16, 19, 26-30, 34-41, 43-44, 48-52, 55 and 59-100 were newly rejected under 35 U.S.C. 102(b) as anticipated by Benveniste and Lagrange et al.

Applicant replied on December 19, 2000, by adding priority information to the specification, amending claims 59, 64, 96-97, 78-85, making minor dependency and/or grammar amendments to a number of claims, canceling claims 15, 26, 48 and 58 and adding claims 106-140 (renumbered as claims 109-143). A number of claims were made multiply dependent. Arguments for each of the rejections were made.

On February 21, 2001, the examiner mailed a new non-final Office action to applicant. The examiner maintained the rejection of claims 5-6, 8-11, 16, 19, 27-30, 34-57, 77 and 86 under 35 U.S.C. 112, second paragraph, for indefiniteness with reasons therefor set forth. The examiner maintained the rejection of claims 5-6, 8-11, 16, 30, 32, 38, 49, 55-57, 59-65, 72 and 74-101 under 35 U.S.C. 112, first paragraph, for lack of written description/new matter in the specification. The examiner maintained the rejection of claims 5-6, 8, 10-11, 16, 19, 27-30, 32-41, 43-44, 46, 48-52 and 55-101 and added claims 103, 106 and 128-143 under 35 U.S.C. 112, first paragraph, as lacking enablement. The examiner maintained the rejection for obvious double patenting for claims 2-14 (sic 5-6, 8 and 10-11), 16-17 (sic 16), 19, 21, 23-25 (sic 25), 27-33, 34-47, 49-55, 56-57 and 101 and added claims 102-143. The rejection of claims 8, 10-11, 16, 19, 27-30, 34-41, 43-44, 46, 49-52, 55, 59-67, 72-73, 76-77, 79, 89-90, 92, 9 (sic 93(?)) and 96-100, and added claims 102, 104-105 and 107-127 under 35 U.S.C. 102(b) as anticipated by Madore et al was maintained. The rejection of claims 5-6, 8, 10-11, 16, 19, 27-30, 34-41, 43-44, 46, 49-52, 59-67, 70-73, 76, 78-79, 90, 92-93 and 96-100, and newly added claims 102, 104-105 and 107-127 under 35 U.S.C. 102(b) as anticipated by Dengrove et al was maintained. The rejection of

claims 5-6, 8, 10-11, 16, 19, 27-30, 32-41, 43-44, 46-47, 49-52, 59-67, 70-73, 76, 78-79, 90-93 and 96-100, and newly added claims 102, 104-105 and 107-127 under 35 U.S.C. 102(b) as anticipated by Halsey et al was maintained. The rejection of claims 5-6, 8, 10-11, 16, 19, 27-30, 32-41, 43-44, 46-47, 49-52, 60-67, 70, 72-73, 78-79, 90-91 and 96-100, and newly added claims 102, 104-105 and 107-127 rejected under 35 U.S.C. 102(b) as anticipated by John was maintained. The rejection of claims 5, 8, 10-11, 16, 19, 27-30, 34-41, 43-44, 46, 49-52, 55 and 59-100, and newly added claims 102, 104-105 and 107-127 rejected under 35 U.S.C. 102(b) as anticipated by Benveniste and Lagrange et al was maintained.

Applicant replied on August 17, 2001, with an amendment canceling claims 69-70, 75-76 and 89 and amending claims 5, 19, 30, 32, 38, 40, 56, 67, 71, 73, 77 and 129, and adding claims 144-152. Responses to each rejection were made. A supplemental amendment was filed September 27, 2001, in which claims 153-265 were added.

On November 5, 2001, the examiner mailed a Final Office action to applicant in which claims 153-155, 158-159 and 161-265 were withdrawn from consideration as being directed to inventions independent and distinct from those originally examined. The examiner maintained the rejection of claims 5-6, 8-11, 16, 27-30, 34-47, 49-57, 77 and 86 under 35 U.S.C. 112, second paragraph, for indefiniteness for reasons of record. The examiner rejected claims 5, 30, 32, 67, 71, 73, 77-85, 144-152 and 157 under 35 U.S.C. 112, second paragraph for new reasons of indefiniteness. The examiner maintained the rejection of claims 5-6, 8, 10-11, 16, 30, 32, 38, 49, 55-57, 59-65, 72 and 74-101 under 35 U.S.C. 112, first paragraph, for lack of written description in the specification for reasons of record. Claims 40 and 145-148 were newly rejected under 35 U.S.C. 112, first paragraph for lack of written description in the specification. The examiner maintained the rejection of claims 5-6, 8, 10-11, 15-16 (sic 16), 19, 27-30, 32-41, 43-44, 46, 48-52 and 55-57, 58-101, 103, 106 and 128-143 under 35 U.S.C. 112, first paragraph, as lacking enablement for reasons of record. Claims 144-152, 156-157 and 160 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The examiner withdrew the rejection for obvious double patenting of claims 2-4 (sic), 16-17 (sic 16), 19, 21, 23-25 (sic 25), 27-21 (sic 31(?)), 24-47 (sic 34-47), 49-55, and 101-127, but maintained the rejection for obvious double patenting for claims 6, 32-33, 56-57, 101, 103 and 128-143 for reasons of record. New claims 144-148, 156-157 and 160 were also rejected for obvious double patenting. The rejection of claims 5-6, 8, 10-11, 16, 19, 27-30, 32-41, 43-44, 46, 49-52, 59-67, 71-73, 78-79, 90-93, 96-100, 102, 104-105 and 107-127 under 35 U.S.C. 102(b) as anticipated by Halsey et al was maintained for reasons of record. The rejection of claims 5-6, 8, 10-11, 16, 19, 27-30, 32-41, 43-44, 46, 49-52, 60-67, 72-73, 78-79, 90-91, 96-100, 102, 104-105 and 107-127 rejected under 35 U.S.C. 102(b) as anticipated by John was maintained for reasons of record. The rejection of claims 5, 8, 10-11, 16, 19, 27-30, 34-41, 43-44, 46, 49-52, 55 and 59-68, 71-74, 77-88, 90-100, 102, 104-105 and 107-127 rejected under 35 U.S.C. 102(b) as anticipated by Benveniste and Lagrange et al was maintained for reasons of record. New claims 149-150 were rejected under 35 U.S.C. 102(b) as anticipated by Madore et al, Dengrove et al, Halsey et al or Benveniste and Lagrange et al. New claims 151-152 were rejected under 35 U.S.C. 102(b) as anticipated by Madore et al, Dengrove et al, Halsey et al, John or Benveniste and Lagrange et al. The examiner also indicated the rejections under 35 U.S.C. 102(b) over Madore et al and John of previously pending claims were withdrawn.

Applicant replied on February 21, 2002, with arguments and proposed amendments. The examiner declined to approve entry of the amendments on the basis that they raise new issues, are directed to new matter and do not place the application in better form for appeal and communicated this to applicant by Advisory action on June 4, 2002.

Applicant filed a new Notice of Appeal on May 6, 2002, and a new amendment after final rejection on June 21, 2002, again proposing amendment of the claims essentially as before with claims 19, 153-158 and 260-265 being canceled and claims 149-152 being amended. In an Advisory action mailed August 20, 2002, the examiner initially denied entry of the amendments for the same reasons as before, however the amendment was later entered. A second amendment after final rejection was also filed June 21, 2002, proposing different amendments to the claims, but was denied entry. A third amendment after final also filed June 21, 2002, and proposing amendments to claims 5, 30, 56, 67, 71, 73 and 144 was initially denied entry, but was later entered. A second Advisory action mailed September 10, 2002, indicated entry of two of the three amendments filed June 21, 2002.

Another amendment after final rejection was filed by applicant on October 18, 2002, accompanied by an extensive affidavit by the inventor under 37 CFR 1.132. The amendment proposed three amendments to the specification and cancellation of claims 159-258 and amended claims 131-136 and 138-143. Entry of the amendment has been approved by the new examiner assigned to the application as indicated in the Advisory action mailed November 18, 2002. However it was also indicated that the affidavit would not be considered as there was no good or sufficient reason given for its late submission.

Applicant filed a new Appeal Brief on November 5, 2002, and a supplement to it to correct a table therein on December 12, 2002. This petition was also filed December 12, 2002.

DISCUSSION

Applicant's petition requests supervisory review under 37 CFR 1.181 and, if necessary, waiver of the Rules under 37 CFR 1.183. Only the petition under 37 CFR 1.181 is being considered in this decision. A petition under 37 CFR 1.183, if warranted, must be presented in a separate paper as the deciding authority for such petitions is the Office of Petitions, not the Technology Center Director.

Applicant presents as part of the petition a brief synopsis of the file history above specifically noting that in the first non-final rejection after the filing of the first Appeal Brief that the examiner made an enablement rejection under 35 U.S.C. 112, first paragraph, and relied on two specific references for support thereof, namely 'PIDJ' and Boumpas et al, both cited by applicant. In rebuttal to applicant's arguments of the rejection and the references relied upon, the examiner further relied upon DeStefano et al, EURODIAB, Graves et al, Heijbel et al, Hultunen et al, Jefferson et al, Karvonen et al, Bedford et al, Petousis-Harris et al, Jefferson T. O., Elliott et al and Anonymous, all cited by applicant, for additional support of the examiners position. In the Final rejection the examiner relied further on applicant's newly submitted, but unpublished,

Clausen and Clausen reference(s) for lack of enablement evidence. In response to the Final Office action issued November 5, 2001, applicant submitted several proposed amendments, some of which were entered and, after filing a Notice of Appeal and further amendments, submitted the affidavit in question on October 18, 2002, more than 11 months after the Final Office action was mailed. Applicant gives four reasons for entry of the declaration which "presents a comprehensive overview of "competing" studies". The reasons given are (1) the exhibits were previously submitted; (2) the exhibits were not published prior to November 5, 2001; (3) the exhibits are responsive to points raised in the final rejection; and (4) the exhibits are newly discovered by applicant. The affidavit is 39 pages long and includes a number of pages of tables as well as a three page listing of cited references of which 11 of 19 are authored or co-authored by applicant. Of the 19 references, 10 are newly submitted with the affidavit and include two unpublished manuscripts, one undated (and unpublished(?)) reference and three references clearly published after the date of the final rejection. These are enumerated by applicant in the petition. The other four newly cited references and nine previously cited references all have publication dates prior to the final rejection.

37 CFR 1.195 states: Affidavits or declarations after appeal.

Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented.

It is clear that this affidavit was submitted several months after the case was appealed. The affidavit contains reference to items not of record, but supplied with the affidavit. These items are not considered to be of the type submitted under 37 CFR 1.97(e), but are part of the affidavit and, unless submitted separately as part of an IDS or cited by the examiner on Form 892, will not be printed on the face of any patent which may issue from this application. The remaining question to be decided is whether applicant has presented good and sufficient reason for admission of the affidavit.

With respect to those items of record or previously published and available prior to the final rejection, such items should have been referenced in the first (or at least an earlier) response to the final rejection. The delay in referencing them until presentation of the affidavit is not a showing of timely presentation thereof in response to the enablement rejection which has been present since the first Office action.

Applicant is correct in noting that 37 CFR 1.116 which relates to entry of amendments after final rejection is of minimal significance here since the Notice of Appeal has already been filed. (Arguments and/or amendments would, however, be considered under 37 CFR 1.116.) The purpose of an affidavit under 37 CFR 1.132 is to present **evidence** relating to patentability of a rejected claim(s). Herein the question of **enablement of the invention** is at question due to a rejection under 35 U.S.C. 112, first paragraph. In making an "enablement" rejection the examiner is stating that the specification, as filed by applicant, does not contain enough information to allow

anyone skilled in the art to make and use the invention. Such rejection is not easily rebutted. However, a showing by reference to articles, reference books, or other items available at the time the invention was made can be used to show that the specification is enabling. It is also possible that references published within a reasonable time after the application was filed could be used to show enablement.

There are two general reasons for an examiner making an enablement rejection. First, the examiner does not understand applicant's teachings in the specification because they appear to be incomplete or inconsistent or the terms used are not understood. Second, the claims are drawn more broadly than the teachings of the specification and the portion of the claim outside the teachings of the specification is not enabled (taught) in the specification. Clearly the first of these types of enablement rejections could be overcome by supplying information which educates the examiner in such a manner as to show that the teachings of the specification are not incomplete or inconsistent or that clarifies the meaning of specific terms. The second type can usually only be overcome by narrowing the claims to conform to the metes and bounds of the specification. Rarely would the latter be overcome by presentation of references and even then the references would have to be contemporary with the filing date of the application. Presentation of affidavit evidence which enables the claims as drawn, but not as supported by the specification disclosure would not serve to overcome the rejection or advance the prosecution of the application. It can only be presumed that the affidavit evidence now presented is of such a nature. Presentation of such evidence, especially recently published evidence, cannot cure the deficiencies of the specification. In fact, presentation of such evidence at such a late stage of prosecution would be more inclined to support the examiner's argument that the specification is non-enabling, as filed. The references already of record have been properly considered by the examiner in response to applicant's previous arguments and need not be presented again in affidavit form. In other words, review of the Final Office action shows no new points or arguments presented by the examiner. Further, the affidavit appears to be more argument rather than presentation of factual evidence or findings which would lead to a determination of patentability.

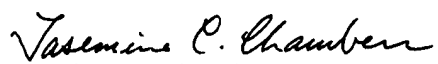
In summary, although applicant has presented some reasons for entry and consideration of the affidavit, the reasons presented are not considered to rise to the level of "good and sufficient" so as to compel entry and consideration of the affidavit. Evidence previously presented and discussed in various responses by applicant has already been considered and evaluated by the examiner and need not be reconsidered. Newly cited references are not likely to add evidence of sufficient weight to cure the deficiencies of the previous presentations, especially with respect to what is supportively enabled by the specification. No new points were raised in the final rejection which would necessitate presentation of the affidavit.

DECISION

Applicants' petition under 37 CFR 1.181 is **DENIED**. The petition under 37 CFR 1.183 is not considered.

The application will be forwarded to the examiner for consideration of the Appeal Brief.

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600, Washington, D.C. 20231, or by telephone at (703)308-3824 or by facsimile transmission at (703) 305-7230.


Jasemine C. Chambers
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